# 510(k) SUMMARY

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**Contact Person:** Shepard G. Bentley
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**Date Prepared:** 16 July 2005

**Device Name:** SureFlow™ Safety Infusion Device

**Trade Name:** SureFlow™ Safety Infusion Device

**Common Name:** Intravascular Administration Set, Needleless

**Classification Name:** Set, Administration, Intravascular

**Device Class:** II (two)

**Procode:** FPA

**CFR Reference:** 880.5440

**Predicate Device:** Multiport® Manifold Set with Swabable Valves, Mode

**Predicate 510(k) #:** K040385

**Device Description:** The SureFlow™ Safety Infusion Device is a needleless, sterile, non-pyrogenic single use intravenous fluid administration set which provides multiple access ports and regulates the directional flow of fluids for simultaneous intravenous therapy. It has 3 ports with swabable luers, integrated check valves, and pre-attached needleless injection ports all connecting to a drip chamber. A 4th port with a swabable luer and pre-attached needleless injection port allows for flushing of the chambers.

It is manufactured with conventional medical grade, biocompatible materials. It operates as a safety device by eliminating the use of needles in the delivery of medications via IV infusion, thus eliminating the opportunity for accidental needlesticks.

In addition, the SureFlow™ aids in reducing nosocomial infections by not requiring a break in the fluid path once the

needleless syringes are connected to the SureFlow™ . The valves are swabbed prior to connection which provides an uninterrupted, sterile fluid path versus the current practice of repetitive access to the IV port with needles which are exposed to airborne contamination.

It is supplied sterile for single use only

**Intended Use:** The SureFlow™ Safety Infusion Device is a device intended to allow a health care practitioner to administer multiple intravenous medications simultaneously to a patient's vascular system utilizing needleless components and an I.V. manifold via syringe, gravity or infusion pump.

It is manufactured with conventional medical grade, biocompatible materials. By being needleless, it operates as a safety device which is designed to aid in reducing the possibility of accidental needle sticks, as well as, aiding in reducing nosocomial infections by not requiring a break in the fluid path once the needleless syringes are connected to the SureFlow™ .

When the infusion is complete, the device is discarded according to the appropriate disposal procedure for the health care provider.

**Technological Comparison:** A summary of the technological characteristics of this device compared to the predicate device can be seen in the Comparison Table in the Specifications Section. This device and the predicate have similar technological characteristics and are substantially equivalent.

**Non-Clinical Data:** The SureFlow™ Safety Infusion Device has been shown to be substantially equivalent to the predicate device by non-clinical performance data. The testing involved performance testing, and biocompatibility testing.


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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2005

Intrasafe Medical, LLC
C/O Mr. Shepard G. Bentley
Regulatory Consultant to Intrasafe Medical, LLC.
Synergy Biomedical, LLC.
28202 Cabot Road, Suite 300
Laguna Niguel, California 92677

Re: K051943
Trade/Device Name: SUREFLOW SAFETY INFUSION DEVICE
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA
Dated: July 16, 2005
Received: July 18, 2005

Dear Mr. Bentley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

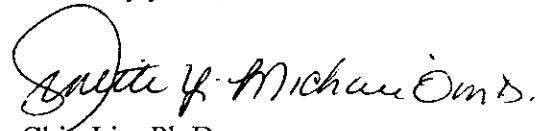
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## *Indications for Use*

510(k) Number (if known): K051943

Device Name: SureFlow™ Safety Infusion Device

Indications for Use:

The SureFlow™ Safety Infusion Device is a device intended to allow a health care practitioner to administer multiple intravenous medications simultaneously to a patient's vascular system utilizing needleless components and an I.V. manifold via syringe, gravity or infusion pump.

By being needleless, it operates as a safety device which is designed to aid in reducing the possibility of accidental needle sticks.

| Prescription Use X | | Over-The-Counter Use |
|---|---|---|
| (Part 21 CFR 801 Subpart D) | AND/OR | (21 CFR 807 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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